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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,715	12/26/2003	Michael Christopher Montalto	133658-2	5857

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GENERAL ELECTRIC COMPANY
GLOBAL RESEARCH
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NISKAYUNA, NY 12309

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/747,715	MONTALTO ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/22/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-61,63-71,73-76 and 78-81* is/are pending in the application.

4a) Of the above claim(s) *65,66,75,76 and 81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-61,63,64,67-71,73,74 and 78-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/22/06 wherein claims 1-57, 62, 72, and 77 are canceled and claims 58, 69, and 81 are amended.

Note: Claims 58-61, 63-71, 73-76, and 78-81 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments and/or amendment filed 11/22/06 to the rejection of the claims made by the Examiner under 35 USC 112 and/or 103 have been fully considered and persuasive because Applicant has amended the claims to overcome the rejection. Therefore, all outstanding rejections are WITHDRAWN.

WITHDRAWN CLAIMS

3. Claims 65, 66, 75, 76, and 81 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b).

NEW GROUNDS OF REJECTIONS

112 Second Paragraph Rejections

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 58-61, 63, 64, 67-71, 73, 74, and 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58-61, 63, 64, 67-71, 73, 74, and 78-80: The claims as written are ambiguous because the variables X, R1, and R2 have not been defined in the claims.

Claims 58-61, 63, 64, 67, and 68: The claims as written are ambiguous because it appears as if essential method steps are missing from independent claim 58. Specifically, it is unclear how one is assessing Alzheimer's disease if the only step is to administer a composition to a subject. In other words, if one just administers a composition to a subject how do you assess Alzheimer's disease without analyzing data obtained from the administer composition?

Claims 58-61, 63, 64, 67-71, 73, 74, and 78-80: The claims as written are ambiguous because based on independent claims 58 and 69, the soluble A-beta is not a required component of the imaging agent. In other words, the claim requires a labeled imaging agent that is capable of binding a soluble A beta. If the claim was written as follows, it would be clear that Applicant intends a soluble A beta component to be present: 'administering to a subject an imaging agent bound to a soluble A beta and a labeled for detection...'.

103 Rejections

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 58-61, 63, 64, 67-71, 73, 74, and 78-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over He et al (US Patent No. 6,784,180) in view of Wu et al (J. Clin. Invest., 1997, Vol. 100, pages 1804-1812).

He et al disclose compounds useful for treating Alzheimer's disease (see the entire document, especially, column 3, lines 44-49). In particular, in column 31, lines 19-49, the preparation of 4-hydroxy-4-(3-(1-hydroxyethyl)benzo[b]thiophen-2-yl)-1-(t-butyloxycarbonyl)piperidine is disclosed. This compound is encompassed within the genus of Applicant's structure when Y = sulfur; R1 = a substituted hydrocarbon radical (i.e., alkyl hydroxyl), and R2 = a substituted hydrocarbon radical (i.e., a substituted heteroaryl). However, He et al fail to disclose that their agent specifically binds to A-beta and that their agent may be radiolabeled.

Wu et al disclose drug targeting of a peptide radiopharmaceutical through the primate blood brain barrier in vivo with a monoclonal antibody to the human insulin receptor. Radiolabeled (125I) A-beta1-40 was monobiotinylated and conjugated to a blood brain barrier drug delivery and brain targeting system comprised of a complex of 83-14 monoclonal antibody which is tagged with streptavidin. After intravenous injection, there was a marked increased in rhesus monkey brain uptake of the radiolabeled pharmaceutical (see entire document, especially, abstract; pages 1805-1806, 'Methods'; page 1807, Figure 5; page Figure 6; page 1809, Figure 8; page 1809,

Figure 9; and page 1810, Figure 11). The A-beta amyloid of tissue sections of Alzheimer's disease can be identified with dyes such as Congo Red or with antibodies directed against certain epitopes of A-beta 1-42/43 peptide. Thus, radiolabeled A-beta 1-40 is a peptide radiopharmaceutical useful for neurodiagnostic quantification of the A-beta amyloid burden in Alzheimer's disease brain of living subjects using standard external detection methodologies such as positron emission tomography (page 1804, column 2, second complete paragraph; pages 1804-1805, bridging paragraph). Hence, both Applicant and Wu et al disclose methods of assessing an amyloid related disease, Alzheimer's disease, comprising administering a subject an imaging agent that binds to A-beta and detecting the imaging agent. However, while Wu et al does not specifically state that the A-beta being detected is soluble, the skilled practitioner in the art would recognize that plaques are composed of insoluble and soluble components. This position is supported by Applicant's disclosure (see Background of the Invention, page 1, paragraph [0003]) which discloses that it is known that plaques are composed mainly of deposited (or insoluble in an aqueous solution) fibrillar forms of beta amyloid (A-beta) peptide. However, recently it has been shown that soluble oligomers (soluble in aqueous buffer) of A-beta could contribute significantly to neuronal dysfunction (see Back of the Invention, page 1, paragraph [0003]). Furthermore, it is noted that Applicant has defined 'A-beta species' as used in the specification to refer to A-beta soluble monomers, soluble oligomer, and insoluble fibrils (see Detailed Description, page 4, paragraph [0013]). Hence, the phrase encompasses both insoluble and soluble A-beta components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of He et al using the teachings of Wu et al and generate a method of assessing Alzheimer's disease because while He et al does not disclose that the agent binds a soluble A-beta component, it would have been obvious to one of ordinary skill because the compound disclosed by He et al is encompassed by the genus of Applicant. Thus, since the compounds of Applicant's genus is capable of binding soluble A-beta, the compound of He et al would also bind soluble A-beta components since a compound is inseparable from its properties. Also, while He et al does not disclose that a labeled isotope may be utilized with their invention, a skilled practitioner in the art would recognize that it is obvious to have a radioisotope because as indicated by Wu et al, using imaging agents comprising radiolabels for evaluating Alzheimer's disease is common in the art. In addition, a skilled practitioner in the art would recognize that a soluble A-beta component such as A-beta 1-40 peptide would be obvious since Wu et al disclose that it is known in the art to utilize this particular peptide for analyzing Alzheimer's disease in a subject.

Since both He et al and Wu et al disclose the analyzing of Alzheimer's disease, one may consider the references to be within the same field of endeavor. Thus, the reference teachings are combinable.

Note: The Examiner has applied Applicant's definitions of 'hydrocarbon radical' as set forth in the specification.

COMMENTS/NOTES

8. The date the amended invention was first disclosed by Applicant is in the instant application. Therefore, Applicant is not entitled to the 5/7/03 filing date of the parent application, 10/431,202.

9. It should be noted that the search of the instant invention was not extended beyond the species above because prior art was found which could be used to reject Applicant's claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

February 8, 2007